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EXAMINER	
STEELE, JENNIFER A	

ART UNIT	PAPER NUMBER
1794	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/802,395	KREIDLER ET AL.	
	Examiner	Art Unit	
	JENNIFER STEELE	1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 January 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-80* is/are pending in the application.

4a) Of the above claim(s) *42-53,62,64-67,69-73 and 75-80* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-41, 54-61,63,68 and 74* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/19/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. **Claim 1-4, 20, 23-39, 54-61, 63 and 74 rejected under 35 U.S.C. 103(a) as being unpatentable over Eldridge et al (US 6,120,539) in view of Shaw et al (US 5,879,366).** The previous Office Action of 10/20/2008 is maintained and presented below.

Eldridge teaches a prothetic repair fabric comprised of a sheet of tissue infiltratable fabric and a second sheet of tissue infiltratable fabric which is fused to an adhesion resistant barrier forming a laminate composite prosthesis without degrading the mechanical properties or tissue ingrowth capability of the first sheet (ABST). Eldridge teaches that prior art prosthetic repair materials have raised the concern that

mesh may form postoperative adhesions with abdominal viscera and to alleviate these concerns it had been proposed to cover the MARLEX mesh with an adhesion resistant barrier such as a sheet of ePTFE (col. 1, lines 16-27). Eldridge teaches the tissue infiltratable fabric is a mesh fabric such as a MARLEX mesh and the adhesion resistant barrier is layer of ePTFE (col. 1, lines 31-38 and col. 4, lines 6-21). Eldridge teaches a process for adhering the ePTFE barrier to the mesh wherein the mesh becomes encapsulated in the submicron porous network of the expanded PTFE sheet. The adhesion resistant barrier layer of ePTFE of Eldridge is equated with the porous first membrane layer. The MARLEX mesh of Eldridge is equated with the open mesh bonding layer. Eldridge differs from the current invention and does not teach a second porous membrane layer.

Shaw teaches a self expanding device for sealing a defect tissue or muscle (col. 1, lines 6-15). Shaw teaches a structure of thin membranes laminated together with an embedded super-elastic wire (col. 2, lines 37-47). Shaw teaches the membranes are of ePTFE cross-laminated to increase membrane strength. Shaw teaches the membranes are porous ePTFE (claim 65).

It would have been obvious to combine the features of the structure of Shaw that has multiple ePTFE membranes with a wire support with structure of Eldridge that teaches a support mesh with a single ePTFE membrane motivated to produce a biocompatible laminate for use in tissue repair that has the desired properties of porosity and resistance to tissue adhesion.

Regarding claim 2 and 37, Eldridge teaches a mesh support structure with only one membrane layer. Shaw teaches multiple membrane layers with an embedded wire support structure. It would have been obvious to combine the features of multiple membrane layers of Shaw with the mesh laminated membrane structure of Eldridge and the results of the combination would have been predictable. This is merely the duplication of parts which provide the same function.

With regards to claim 3, 4, 38 and 39, Eldridge teaches the laminate is porous and is intended for tissue growth and attachment and Eldridge teaches physical and performance characteristics were tested such as pore size, surface roughness, suture retention strength and burst strength (col. 5, lines 14-19). Eldridge teaches In-Vivo testing for tissue ingrowth (col. 6, lines 10-40).

As to claim 20, Eldridge teaches an average spacing between the mesh pores of 0.125 inches (col. 3, lines 47).

Regarding claim 23-25, Eldridge teaches a monofilament polypropylene which would have a melting point of 177°C (350°F). Eldridge teaches a process where the laminate is heated to a temperature of 350-400°F which is equal to 176 to 204°C. Applicant teaches a process where the laminate is heated to a temperature that is greater than the softening temperature of the bonding layer and less that the membranes and that temperature is in the range of 100 to 300 degree Celsius [0102]. The bonding layer softening point of Eldridge is equated with the bonding layer softening point of the current application.

As to claims 26, Eldridge teaches an ePTFE layer of thickness 0.0035 inches which is in the range of claim 26.

As to claim 27, Eldridge differs and does not teach an ePTFE membrane layer thickness of 0.001 to 0.002 inches. Shaw teaches ePTFE membranes that can have a thicknesses in the range of approximately 0.0025 mm to 0.025 mm thick which is equal to 0.0001 to 0.001 inches and in the range of the membrane thicknesses that are claim 27.

Regarding claim 28 and 29, Eldridge differs and does not teach the property of open surface area of the membrane. Eldridge teaches the ePTFE membranes have a surface pore size of 0.74 +/- 0.3 microns (Table 1, col. 6). As Eldridge is teaches a membrane biocompatible laminate comprised of ePTFE which is the same materials and structure as the claimed invention, it is presumed that the property of surface area would be inherent to the structure of the claimed invention.

As to claims 30-35, Eldridge teaches the same membrane material as the Applicant, the property of softening point is presumed to be the same as the Applicants. Eldridge further teaches that the bonding layer or knit mesh melts and becomes encapsulated in the porous network of the PTFE sheet and therefore teaches that the bonding layer is of a lower melting temperature than the membrane.

Regarding claims 36-39, Eldridge laminate material is implantable and therefore, the above rejection of Eldridge in view of Shaw meets the new limitation of an implantable medical device comprising a biocompatible laminate.

As to claims 54-60, Eldridge in view of Shaw teaches a laminate membrane for use as a medical device comprising a first membrane a bonding mesh layer and a second membrane as noted above. Eldridge in view of Shaw differ from the current application and does not teach the property of open surface area in the range between about 10-50%. However as the laminate of Eldridge in view of Shaw teaches the structure and materials of the claimed in invention, it is presumed that the property of open surface area would be inherent in this structure.

As to claim 55, Eldridge teaches an ePTFE membrane.

As to claim 56 , Eldridge teaches a membrane of a thickness of 0.0035 inches.

As to claim 57, Eldridge teaches a pore size of 0.74 +/- 0.3 micron which could be 1.04 micron and therefore encompasses the claimed range about 1 micron to about 200 micron.

As to claim 58, Eldridge differs and does not disclose the internodal distance in the membrane. As Eldridge teaches the same materials and structure of the claimed invention, it is presumed that the property of internodal distance is inherent to the structure of the ePTFE membrane of Eldridge.

As to claim 59, Eldridge teaches a mesh bonding layer comprised of polypropylene and differs and does not teach a polyethylene mesh bonding layer. Shaw teaches membrane layers that can be manufactured of polyester, polyethylene, polypropylene, fluoropolymers, polyurethane foamed films, silicone, nylon, silk, thin sheets of super-elastic materials, woven materials or any other biocompatible materials

(col. 4, lines 58-68). It would have been obvious to substitute polyethylene for polypropylene in the bonding layer mesh.

As to claim 60, Eldridge teaches a laminate of a thickness of 0.0635 inches which is in the range of claim 60.

Regarding claims 61, 63 and 74 that are drawn to a medical device comprising a frame wherein the frame is configured for use as a stent, Eldridge differs from the current application and does not teach a frame or a laminate for a stent. Shaw teaches a composite laminate that is configured with an elastic wire frame structure so that the device can be collapsed and then expanded. Shaw teaches a star shaped wire frame for a defect closure device as shown in Fig. 1 (col. 5, lines 28-40).

2. **Claim 5-19, 21, 22, and 40-41 rejected under 35 U.S.C. 103(a) as being unpatentable over Eldridge et al (US 6,120,539) in view of Shaw et al (US 5,879,366) and in further view of Notaras et al (WO 9603091).**

As to claims 5-9, and 40-41, Eldridge teaches a laminate wherein the mesh fabric has a thickness of 0.06 inches and a membrane with a 0.0035 inch thickness and an overall thickness of 0.0635 inches. The thickness of Eldridge is greater than the claimed invention because the mesh is thicker than the claimed invention.

Shaw teaches the membranes are each approximately 0.0025 mm to 0.025 mm thick which is equal to 0.0001 to 0.001 inches. While Shaw laminates of 2,4,6, 8 and 10 plies, Shaw teaches a total laminate thickness between 0.0002 to 0.002 which overlaps the range of the claimed invention. Shaw presents a finding to one of ordinary skill in

the art that a biocompatible membrane with layer thicknesses in the range 0.001 to 0.010 inches and less than 0.005 and 0.003 and 0.002 could be employed with a reasonable expectation of success. As Shaw teaches the individual layer thicknesses of the ePTFE film in the range of 0.0002 to 0.002 inches and teaches that a range of plies can be employed, Shaw teaches a laminate that could be no more that 2 or 3 times the first or second membrane layer thicknesses.

Notaras teaches a surgical mesh of substantially uniform thickness that is useful for hernia repair and abdominal wall reinforcement (page 1, lines 1-5). Notaras teaches the mesh thickness is from 0.05 to 2 mm thick which is 0.0019 inches to 0.078 inches thick.

It would have been obvious to one of ordinary skill in the art to employ a membrane laminate with an overall thickness as taught by Shaw employing a structural mesh of thickness as taught by Notaras motivated to produce a thin laminate for tissue repair. As Shaw and Notaras teach that it is known in the art to produce a membrane laminate and mesh of thicknesses in the range of the claimed invention, one of ordinary skill in the art could have combined the elements with a reasonable expectation of success.

Regarding claims 14-17, Eldridge in view of Shaw differ and do not teach a mesh bonding layer with an average thickness of 0.0005 to 0.005 inches. Notaras teaches a surgical mesh with a thickness of 0.0019 to 0.078 inches which is in the claimed ranges of 0.0008 to 0.004 inches and 0.0009 to 0.003 inches and 0.001 to 0.002 inches. It

would have been obvious to one of ordinary skill in the art to employ the mesh of Notaras motivated to produce a surgical laminate of the desired thickness.

With respect to claims 18-19, Eldridge teaches a mesh bonding layer that has a knit structure with a predetermined spacing pattern (col. 3, lines 42-50) but differs and does not teach the average pore cross-section. Notaras teaches a surgical mesh with a pore size that may be determined according to the use of the mesh for a particular operation. Notaras teaches it may be above 100 micron such as 0.5 to 10 mm, preferably 1.5 to 4 mm (page 4, lines 26-36). Notaras teaches a mesh that is 0.019 inches to 0.39 inches, preferably 0.06 inches to 0.16 inches. It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ a mesh with a pore size as taught by Notaras motivated to produce the desired properties of strength, porosity and adhesion in the laminate.

As to claims 21 and 22, Eldridge in view of Shaw and Notaras differ and do not teach the feature of open surface area of the bonding layer. Eldridge teaches the spacing between the pores can be 0.125 inches and in the range of the claimed invention. Notaras teaches a mesh with an average pore size in the range of the claimed invention and teaches the pore sized may be determined according to the use for the particular operation. However as Eldridge and Notaras teach the structure and materials of the claimed invention, it is presumed that the feature of open surface area would be inherent to the meshes of prior art and therefore it would have been obvious to employ a bonding mesh with an average open surface area of 10-90% and 30- 60% motivated to produce the desired properties of strength, porosity and adhesion.

Response to Arguments

3. Applicant's arguments filed 1/19/2008 have been fully considered but they are not persuasive. The previous 35 USC 103 rejection over Etheridge in view of Shaw is maintained. Applicant argues that the Examiner has failed to provide explicit explanations supporting the obviousness rejections and failed to identify (1) the knowledge one skilled in the art would possess, (2) what modifications the skilled person would need to make to combine the prior art references and (3) whether that skilled person would have a reasonable expectation of success.

Examiner maintains that the 35 USC 103 rejection over Eldridge in view of Shaw is proper and commensurate with the scope of the claims. Both the references to Eldridge and Shaw are directed at biocompatible laminate fabrics and therefore encompass the level of knowledge one skilled in the art would possess. The modification to Etheridge is to employ a secondary membrane layer. While Examiner relied upon Shaw for teaching a multilayer membrane that is biocompatible and for use in repairing or sealing a septal defect, Eldridge teaches the polypropylene monofilament fabric can be formed out of PROLENE, SOFT TISSUE PATCH (a porous ePTFE). Examiner maintains that the skilled person would have a reasonable expectation of success in producing the claimed biolaminate fabric.

4. Applicant has not presented any evidence that the structure of the claimed invention has an unexpected result and as the combination of Eldridge and Shaw meet

the structural and material limitations of the claims, it would have been obvious to combine the known features and the results of the combination would have a reasonable expectation of success in produced a biocompatible laminate for use in repairing and sealing tears in tissue.

5. Applicant argues that Eldridge's barrier layer, which is the membrane layer discourages tissue in-growth and viscera adhesion. And Shaw's design seals a defect by positioning a membrane on both sides of the defect. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., tissue in-growth of the membrane) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Examiner recognizes that Applicant's claims recite the "biocompatible laminate fabric retains sufficient porosity to facilitate cellular growth and cellular attachment" in claims 2 and 3, however Eldridge teaches a laminate fabric of tissue infiltratable fabric (col. 2, lines 20) and an adhesion resistant barrier. The composite of Eldridge has the property of being tissue infiltratable which is equated with cellular ingrowth and cellular attachment. Therefore Eldridge meets the claimed limitation. "Though understanding the claim language may be aided by explanations contained in the written description, it is important not to import into a claim limitations that are not part of the claim. For example, a particular embodiment appearing in the written description may not be read

into a claim when the claim language is broader than the embodiment." MPEP 2111.01 [R-5] I.

6. Applicant argues that with regard to claim 54, Eldridge and Shaw do not teach the property of "open surface area in the range between about 10% and 50%". One of ordinary skill in the art would know that a membrane would inherently have a pore size and would result in an open surface area. For example as evidenced by the Encyclopedia of Polymer and Science article entitled Membrane Technology (reference is included) which teaches that membranes are designed to work as filters but at a micron level and are designed to have a pore size. When the structure has a surface pore size, the surface would have a surface open area and the property would be inherent in the structure.

The membrane of Eldridge has a surface pore size of 0.74 microns and is measured in a 10x10 micron sample. The number of pores in the 10x10 micron sample comprising the mean value (of 0.74 micron) ranged from 6-100 for each sample. Calculating the surface area of the 0.74 micron pores would result in approximately 14% open pore surface area (calculated as [area of pores $(0.74/2)^2$] x [100 pores] / [area of sample 100 $micron^2$] x 100 = 14%). Therefore Eldridge meets this limitation.

The Applicant teaches a pore size of the barrier layer **15** in the specification of 5 micron to 60 micron [0087] which is substantially larger than the barrier layer pore size of Eldridge. However, Applicant is not claiming the pore size of the barrier membrane and therefore Applicant's invention would be obvious over the teachings of Eldridge in

view of Shaw. "Though understanding the claim language may be aided by explanations contained in the written description, it is important not to import into a claim limitations that are not part of the claim. For example, a particular embodiment appearing in the written description may not be read into a claim when the claim language is broader than the embodiment." MPEP 2111.01 [R-5] I.

7. Applicant's arguments regarding claim 61 are not persuasive. Applicants argue that the combination of Eldridge and Shaw can not be properly combined because the combination would frustrate the purpose of each of the references. Claim 61 is directed to a laminated medical device suitable for implantation which both references to Eldridge and Shaw teach. Claim 61 includes the limitation of claim 54 wherein the composite membrane has open surface area in the range between about 10% and about 50%. As noted in paragraph 4 above, Eldridge meets this limitation.

8. Applicant's argues claim 74 limitation "wherein the stent is generally cylindrical and is adjustable from a first configuration having a reduced diameter to a second configuration having a second configuration having an expanded diameter, the stent forming a conduit in the second configuration" is not met by either Eldridge or Shaw. Examiner relied upon Shaw for teaching a structure that collapses in order to be put in place for repair and then expands when in place. Shaw teaches a wire that is equated with the claimed frame. Shaw teaches a circular structure which would have a diameter and therefore Shaw teaches this limitation. As the claim is recited, Eldridge in view of

Shaw teach the claimed structure and function. Webster's dictionary definition of a stent is : a short narrow metal or plastic tube often in the form of a mesh that is inserted into the lumen of an anatomical vessel (as an artery or a bile duct) especially to keep a previously blocked passageway open. Shaw teaches a circular structure which would have a diameter and Shaw teaches a wire that serves as a frame and therefore Shaw teaches this limitation.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNIFER STEELE whose telephone number is (571)272-7115. The examiner can normally be reached on Office Hours Mon-Fri 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Rena Dye can be reached on (571) 272-3186. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. S./
Examiner, Art Unit 1794

/Elizabeth M. Cole/
Primary Examiner, Art Unit 1794

4/17/2009